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Attorneys for Defendants

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

IN RE: Bard IVC Filters Products Liability MDL NO. 15-02641-PHX-DGC
Litigation

This Document Relates to:

NORMA J. DUKETT,

Plaintiff,

Case No. CV-15-2303-PHX-DGC

v.

C. R. BARD, INC., a New Jersey
Corporation; AND BARD PERIPHERAL
VASCULAR INC., an Arizona
Corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND AFFIRMATIVE
DEFENSES AND DEMAND FOR
TRIAL BY JURY**

Defendants.

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV")
(Bard and BPV are collectively "Defendants") answer the Complaint ("Plaintiff's
Complaint") of Plaintiff Norma J. Dukett ("Plaintiff") as follows:

INTRODUCTORY ALLEGATIONS

1
2 1. Defendants deny the allegations contained in Paragraph 1 of Plaintiff's
3 Complaint.

4 2. Defendants admit that Bard is a New Jersey Corporation and that Bard is
5 authorized to do business, and does business, in the State of Illinois. Defendants admit that
6 Bard owns a facility where vena cava filters are manufactured, including filters that were
7 manufactured under the trademark Recovery® Filter System. Defendants deny any
8 remaining allegations contained in Paragraph 2 of Plaintiff's Complaint.

9 3. Defendants admit that BPV is an Arizona Corporation and that BPV is
10 authorized to do business, and does business, in the State of Illinois. Defendants further
11 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
12 has designed, sold, marketed, and distributed filters under the trademark Recovery® Filter
13 System. Defendants further admit that BPV is a wholly owned subsidiary of Bard.
14 Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiff's Complaint.

15 4. The allegations of Paragraph 4 of Plaintiff's Complaint are not directed to Bard
16 or BPV and, as a result, require no response by Defendants. However, to the extent
17 Paragraph 4 purports to cast liability either directly or indirectly upon Defendants, said
18 Paragraph is expressly denied.

19 5. Defendants deny the allegations contained in Paragraph 5 of Plaintiff's
20 Complaint.

21 6. Defendants deny the allegations contained in Paragraph 6 of Plaintiff's
22 Complaint.

23 7. Defendants admit that Bard is a New Jersey Corporation and that Bard is
24 authorized to do business, and does business, in the State of Illinois. Defendants admit that
25 BPV is an Arizona Corporation and that BPV is authorized to do business, and does business,
26 in the State of Illinois. Defendants deny any remaining allegations contained in Paragraph 7
27 of Plaintiff's Complaint that are directed to Defendants.
28

confirmed by Defendants, venue appears to be proper in the United States District Court for the Central District of Illinois.

FACTUAL ALLEGATIONS

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny the remaining allegations contained in Paragraph 13 of Plaintiff's Complaint.

14. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants further admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants deny any remaining allegations contained in Paragraph 14 of Plaintiff's Complaint.

15. Defendants deny the allegations contained in Paragraph 15 of Plaintiff's Complaint.

16. Defendants deny the allegations contained in Paragraph 16 of Plaintiff's Complaint.

17. Defendants deny the allegations contained in Paragraph 17 of Plaintiff's Complaint.

18. Defendants deny the allegations contained in Paragraph 18 of Plaintiff's Complaint.

19. Defendants deny the allegations contained in Paragraph 19 of Plaintiff's Complaint.

20. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first

1 introduced on the market or the identity of manufacturers of inferior vena cava filters.
2 Defendants deny any remaining allegations of Paragraph 20 of Plaintiff's Complaint.

3 21. Defendants admit that inferior vena cava filters are intended to prevent injury or
4 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
5 that inferior vena cava filters may be designed for permanent placement, temporary
6 placement, or both. Defendants deny any remaining allegations of Paragraph 21 of Plaintiff's
7 Complaint.

8 22. Defendants admit that the inferior vena cava is a large vein that receives blood
9 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
10 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
11 human health, including sometimes death. Defendants deny any remaining allegations of
12 Paragraph 22 of Plaintiff's Complaint.

13 23. Defendants admit that patients at a high risk for developing deep vein
14 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
15 including but not limited to the medications listed in Paragraph 23 of Plaintiff's Complaint.
16 Defendants further admit that inferior vena cava filters may also be used to treat patients who
17 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
18 lack knowledge or information sufficient to form a belief as to the truth of any remaining
19 allegations contained in Paragraph 23 of Plaintiff's Complaint and, on that basis, deny them.

20 24. Defendants lack knowledge or information or information sufficient to form a
21 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
22 were first introduced on the market. Defendants also lack knowledge or information
23 sufficient to form a belief as to the truth of the allegation regarding the time frame when
24 optional or retrievable filters came to be marketed or the other allegations regarding optional
25 or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®
26 Filter was cleared by the FDA for optional use as a retrievable inferior vena cava filter.

1 Defendants deny any remaining allegations contained in Paragraph 24 of Plaintiff's
2 Complaint.

3 25. Defendants admit that Bard has distributed the Simon Nitinol Filter in the
4 United States since at least 1992. Defendants further admit that the Recovery® Filter was
5 cleared by the FDA for optional use as a retrievable inferior vena cava filter. Defendants
6 deny any remaining allegations contained in Paragraph 25 of Plaintiff's Complaint.

7 26. Defendants admit that in the 510(k) submission submitted by Bard on or about
8 July 10, 2002, Bard stated to the FDA that the Recovery® Filter is "substantially equivalent"
9 -- as that term of art is used by the FDA and as it is defined in the Code of Federal
10 Regulations -- to the Simon Nitinol Filter/Straight Line™ System (cleared by the FDA on or
11 about April 28, 1995; K944353), and on November 27, 2002, the FDA issued a letter
12 indicating that it concurred. Defendants deny any remaining allegations contained in
13 Paragraph 26 of Plaintiff's Complaint.

14 27. Defendants admit that the Recovery® Filter was cleared by the FDA for
15 retrievable placement on July 25, 2003, pursuant to an application submitted under
16 Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining
17 allegations contained in Paragraph 27 of Plaintiff's Complaint.

18 28. Defendants deny the allegations contained in Paragraph 28 of Plaintiff's
19 Complaint.

20 29. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
21 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
22 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
23 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
24 allegations contained in Paragraph 29 of Plaintiff's Complaint.

25 30. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
26 manufacture of the Recovery® Filter and further admit that Nitinol contains shape memory.

1 However, to the extent Paragraph 30 purports to cast liability either directly or indirectly
2 upon Defendants, said Paragraph is expressly denied.

3 31. Defendants admit that the Recovery® Filter was designed to be inserted
4 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
5 delivered via an introducer sheath, which is included in the delivery system for the device.
6 Defendants deny any remaining allegations of Paragraph 31 of Plaintiff's Complaint.

7 32. Defendants deny the allegations contained in Paragraph 32 of Plaintiff's
8 Complaint.

9 33. Defendants deny the allegations contained in Paragraph 33 of Plaintiff's
10 Complaint.

11 34. Defendants deny the allegations contained in Paragraph 34 of Plaintiff's
12 Complaint.

13 35. Defendants deny the allegations contained in Paragraph 35 of Plaintiff's
14 Complaint.

15 36. Defendants deny the allegations contained in Paragraph 36 of Plaintiff's
16 Complaint.

17 37. Defendants deny the allegations contained in Paragraph 37 of Plaintiff's
18 Complaint.

19 38. Defendants admit that there are various well-documented complications that
20 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
21 Defendants further admit that it is well documented that many instances of filter fracture
22 and/or migration result in no complications whatsoever but, rather, are completely
23 asymptomatic. By way of further response, Bard states that there are incidents related to the
24 occurrence of known complications associated with every manufacturer of inferior vena cava
25 filters. Defendants deny the remaining allegations of Paragraph 38 of Plaintiff's Complaint,
26 including all sub-parts thereof.
27
28

1 39. Defendants admit that there are various well-documented complications that
2 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
3 Defendants further admit that it is well documented than many instances of filter fracture
4 and/or migration result in no complications whatsoever but, rather, are completely
5 asymptomatic. By way of further response, Bard states that there are incidents related to the
6 occurrence of known complications associated with every manufacturer of inferior vena cava
7 filters. Defendants deny the remaining allegations of Paragraph 39 of Plaintiff's Complaint,
8 including all sub-parts thereof.

9 40. Defendants deny the allegations contained in Paragraph 40 of Plaintiff's
10 Complaint.

11 41. Defendants deny the allegations contained in Paragraph 41 of Plaintiff's
12 Complaint.

13 42. Defendants deny the allegations contained in Paragraph 42 of Plaintiff's
14 Complaint, including all sub-parts thereof.

15 43. Defendants deny the allegations contained in Paragraph 43 of Plaintiff's
16 Complaint.

17 44. Defendants deny the allegations contained in Paragraph 44 of Plaintiff's
18 Complaint.

19 45. Defendants deny the allegations contained in Paragraph 45 of Plaintiff's
20 Complaint.

21 46. Defendants deny the allegations contained in Paragraph 46 of Plaintiff's
22 Complaint.

23 47. Defendants deny the allegations contained in Paragraph 47 of Plaintiff's
24 Complaint.

25 48. Defendants deny the allegations contained in Paragraph 48 of Plaintiff's
26 Complaint.

1 49. Defendants deny the allegations contained in Paragraph 49 of Plaintiff's
2 Complaint.

3 50. Defendants deny the allegations contained in Paragraph 50 of Plaintiff's
4 Complaint, including all sub-parts thereof.

5 51. Defendants deny the allegations contained in Paragraph 51 of Plaintiff's
6 Complaint, including all sub-parts thereof.

7 52. Defendants deny the allegations contained in Paragraph 52 of Plaintiff's
8 Complaint.

9 53. Defendants deny the allegations contained in Paragraph 53 of Plaintiff's
10 Complaint as stated. By way of further response, Defendants admit that, as part of their
11 continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the
12 ever-changing state-of-the-art, they are continually striving to improve the life-saving
13 performance of those devices. In this regard, and pursuant to an application submitted under
14 Section 510(k) of the Food, Drug and Cosmetic Act, BPV received FDA clearance on
15 August 24, 2011, for the Meridian® Filter, which has caudal anchors on the six filter "arms."
16 Defendants deny the remaining allegations of Paragraph 53 of Plaintiff's Complaint.

17 54. Defendants deny the allegations contained in Paragraph 54 of Plaintiff's
18 Complaint.

19 55. Defendants deny the allegations contained in Paragraph 55 of Plaintiff's
20 Complaint.

21 56. Defendants deny the allegations contained in Paragraph 56 of Plaintiff's
22 Complaint.

23 57. Defendants deny the allegations contained in Paragraph 57 of Plaintiff's
24 Complaint.

25 58. Defendants deny the allegations contained in Paragraph 58 of Plaintiff's
26 Complaint.

1 59. Defendants deny the allegations contained in Paragraph 59 of Plaintiff's
2 Complaint.

3 60. Defendants deny the allegations contained in Paragraph 60 of Plaintiff's
4 Complaint.

5 61. Defendants deny the allegations contained in Paragraph 61 of Plaintiff's
6 Complaint.

7 62. Defendants deny the allegations contained in Paragraph 62 of Plaintiff's
8 Complaint.

9 63. Defendants deny the allegations contained in Paragraph 63 of Plaintiff's
10 Complaint.

11 64. Defendants deny the allegations contained in Paragraph 64 of Plaintiff's
12 Complaint.

13 65. Defendants deny the allegations contained in Paragraph 65 of Plaintiff's
14 Complaint.

15 66. Defendants deny the allegations contained in Paragraph 66 of Plaintiff's
16 Complaint.

17 67. Defendants are without knowledge or information sufficient to form a belief as
18 to the truth of the allegations regarding the trade name of any inferior vena cava filter
19 implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining
20 allegations of Paragraph 67 of Plaintiff's Complaint.

21 68. Defendants admit that Bard owns a facility where vena cava filters are
22 manufactured and that filters under the trademark Recovery® Filter System were
23 manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and
24 distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed
25 filters under the trademark Recovery® Filter System. Defendants deny any remaining
26 allegations of Paragraph 68 of Plaintiff's Complaint.

69. Defendants deny the allegations contained in Paragraph 69 of Plaintiff's Complaint.

70. Defendants deny the allegations contained in Paragraph 70 of Plaintiff's Complaint.

FIRST CAUSE OF ACTION

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

71. Defendants incorporate by reference their responses to Paragraphs 1-70 of Plaintiff's Complaint as if fully set forth herein.

72. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants deny any remaining allegations contained in Paragraph 72 of Plaintiff's Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiff's Complaint.

74. Defendants deny the allegations contained in Paragraph 74 of Plaintiff's Complaint.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiff's Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of Plaintiff's Complaint.

Further responding to the unnumbered Paragraph following Paragraph 76 and beginning "Wherefore," Defendants aver that Plaintiff is not entitled to the relief demanded in

1 this Paragraph, and these Defendants, having answered fully, pray that this action against
 2 them be dismissed and that they be awarded their costs in defending this action and that they
 3 be granted such other and further relief as the Court deems just and appropriate.

4 **SECOND CAUSE OF ACTION**

5 **STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

6 77. Defendants incorporate by reference their responses to Paragraphs 1-76 of
 7 Plaintiff's Complaint as if fully set forth herein.

8 78. Defendants are without knowledge or information sufficient to form a belief as
 9 to the truth of the allegations regarding the trade name of any inferior vena cava filter
 10 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
 11 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
 12 the trademark Recovery® Filter System were manufactured at that facility. Defendants
 13 further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and
 14 that BPV designed, sold, marketed, and distributed filters under the trademark Recovery®
 15 Filter System. Defendants deny any remaining allegations contained in Paragraph 78 of
 16 Plaintiff's Complaint.

17 79. Defendants deny the allegations contained in Paragraph 79 of Plaintiff's
 18 Complaint.

19 80. Defendants deny the allegations contained in Paragraph 80 of Plaintiff's
 20 Complaint.

21 81. Defendants deny the allegations contained in Paragraph 81 of Plaintiff's
 22 Complaint.

23 82. Defendants deny the allegations contained in Paragraph 82 of Plaintiff's
 24 Complaint.

25 83. Defendants deny the allegations contained in Paragraph 83 of Plaintiff's
 26 Complaint.

Further responding to the unnumbered Paragraph following Paragraph 83 and beginning “Wherefore,” Defendants aver that Plaintiff is not entitled to the relief demanded in that Paragraph, and these Defendants, having answered fully, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

THIRD CAUSE OF ACTION

NEGLIGENCE -- DESIGN, MANUFACTURE, SALE

84. Defendants incorporate by reference their responses to Paragraphs 1-83 of Plaintiff’s Complaint as if fully set forth herein.

85. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants deny any remaining allegations contained in Paragraph 85 of Plaintiff’s Complaint.

86. Defendants deny the allegations contained in Paragraph 86 of Plaintiff’s Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of Plaintiff’s Complaint, including all sub-parts thereof.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiff’s Complaint, including all sub-parts thereof.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiff’s Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of Plaintiff's Complaint.

97. Defendants deny the allegations contained in Paragraph 97 of Plaintiff's Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of Plaintiff's Complaint.

Further responding to the unnumbered Paragraph following Paragraph 98 and beginning “Wherefore,” Defendants aver that Plaintiff is not entitled to the relief demanded in that Paragraph, and these Defendants, having answered fully, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

FIFTH CAUSE OF ACTION

NEGLIGENCE -- FAILURE TO WARN

99. Defendants incorporate by reference their responses to Paragraphs 1-98 of Plaintiff's Complaint as if fully set forth herein.

100. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Recovery® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Recovery® Filter System. Defendants deny any remaining allegations contained in Paragraph 100 of Plaintiff's Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiff's Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiff's Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiff's Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of Plaintiff's Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiff's Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of Plaintiff's Complaint.

Further responding to the unnumbered Paragraph following Paragraph 106 and beginning “Wherefore,” Defendants aver that Plaintiff is not entitled to the relief demanded in that Paragraph, and these Defendants, having answered fully, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

SIXTH CAUSE OF ACTION

NEGLIGENT MISREPRESENTATION

107. Defendants incorporate by reference their responses to Paragraphs 1-106 of Plaintiff's Complaint as if fully set forth herein.

108. Defendants deny the allegations contained in Paragraph 108 of Plaintiff's Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of Plaintiff's Complaint.

110. Defendants deny the allegations contained in Paragraph 110 of Plaintiff's Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of Plaintiff's Complaint.

Further responding to the unnumbered Paragraph following Paragraph 111 and beginning “Wherefore,” Defendants aver that Plaintiff is not entitled to the relief demanded in that Paragraph, and these Defendants, having answered fully, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

SEVENTH CAUSE OF ACTION

BREACH OF EXPRESS IMPLIED WARRANTY

112. Defendants incorporate by reference their responses to Paragraphs 1-111 of Plaintiff’s Complaint as if fully set forth herein.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiff’s Complaint.

114. Defendants deny the allegations contained in Paragraph 114 of Plaintiff’s Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of Plaintiff’s Complaint.

116. Defendants deny the allegations contained in Paragraph 116 of Plaintiff’s Complaint.

Further responding to the unnumbered Paragraph following Paragraph 116 and beginning “Wherefore,” Defendants aver that Plaintiff is not entitled to the relief demanded in that Paragraph, and these Defendants, having answered fully, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

EIGHTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE

117. Defendants incorporate by reference their responses to Paragraphs 1-116 of Plaintiff’s Complaint as if fully set forth herein.

1 118. Defendants deny the allegations contained in Paragraph 118 of Plaintiff's
2 Complaint.

3 119. Defendants deny the allegations contained in Paragraph 119 of Plaintiff's
4 Complaint.

5 120. Defendants deny the allegations contained in Paragraph 120 of Plaintiff's
6 Complaint.

7 121. Defendants deny the allegations contained in Paragraph 121 of Plaintiff's
8 Complaint.

9 122. Defendants deny the allegations contained in Paragraph 122 of Plaintiff's
10 Complaint.

11 123. Defendants deny the allegations contained in Paragraph 123 of Plaintiff's
12 Complaint.

13 124. Defendants deny the allegations contained in Paragraph 124 of Plaintiff's
14 Complaint.

15 Further responding to the unnumbered Paragraph following Paragraph 124 and
16 beginning "Wherefore," Defendants aver that Plaintiff is not entitled to the relief demanded in
17 that Paragraph, and these Defendants, having answered fully, pray that this action against
18 them be dismissed and that they be awarded their costs in defending this action and that they
19 be granted such other and further relief as the Court deems just and appropriate.

20 **NINTH CAUSE OF ACTION**

21 **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

22 125. Defendants incorporate by reference their responses to Paragraphs 1-124 of
23 Plaintiff's Complaint as if fully set forth herein.

24 126. Defendants deny the allegations contained in Paragraph 126 of Plaintiff's
25 Complaint.

26 127. Defendants deny the allegations contained in Paragraph 127 of Plaintiff's
27 Complaint.

1 128. Defendants deny the allegations contained in Paragraph 128 of Plaintiff's
2 Complaint.

3 129. Defendants deny the allegations contained in Paragraph 129 of Plaintiff's
4 Complaint.

5 130. Defendants deny the allegations contained in Paragraph 130 of Plaintiff's
6 Complaint.

7 Further responding to the unnumbered Paragraph following Paragraph 130 and
8 beginning "Wherefore," Defendants aver that Plaintiff is not entitled to the relief demanded in
9 that Paragraph, and these Defendants, having answered fully, pray that this action against
10 them be dismissed and that they be awarded their costs in defending this action and that they
11 be granted such other and further relief as the Court deems just and appropriate.

12 **TENTH CAUSE OF ACTION**

13 **FRAUD – MISREPRESENTATION**

14 131. Defendants incorporate by reference their responses to Paragraphs 1-130 of
15 Plaintiff's Complaint as if fully set forth herein.

16 132. Defendants deny the allegations contained in Paragraph 132 of Plaintiff's
17 Complaint, including all sub-parts thereof.

18 133. Defendants deny the allegations contained in Paragraph 133 of Plaintiff's
19 Complaint.

20 134. Defendants deny the allegations contained in Paragraph 134 of Plaintiff's
21 Complaint.

22 135. Defendants deny the allegations contained in Paragraph 135 of Plaintiff's
23 Complaint.

24 136. Defendants deny the allegations contained in Paragraph 136 of Plaintiff's
25 Complaint.

26 137. Defendants deny the allegations contained in Paragraph 137 of Plaintiff's
27 Complaint.

1 138. Defendants deny the allegations contained in Paragraph 138 of Plaintiff's
2 Complaint.

3 139. Defendants deny the allegations contained in Paragraph 139 of Plaintiff's
4 Complaint.

5 140. Defendants deny the allegations contained in Paragraph 140 of Plaintiff's
6 Complaint.

7 141. Defendants deny the allegations contained in Paragraph 141 of Plaintiff's
8 Complaint.

9 142. Defendants deny the allegations contained in Paragraph 142 of Plaintiff's
10 Complaint.

11 143. Defendants deny the allegations contained in Paragraph 143 of Plaintiff's
12 Complaint.

13 Further responding to the unnumbered Paragraph following Paragraph 143 and
14 beginning "Wherefore," Defendants aver that Plaintiff is not entitled to the relief demanded in
15 that Paragraph, and these Defendants, having answered fully, pray that this action against
16 them be dismissed and that they be awarded their costs in defending this action and that they
17 be granted such other and further relief as the Court deems just and appropriate.

18 **ELEVENTH CAUSE OF ACTION**

19 **FRAUD – CONCEALMENT**

20 144. Defendants incorporate by reference their responses to Paragraphs 1-143 of
21 Plaintiff's Complaint as if fully set forth herein.

22 145. Defendants deny the allegations contained in Paragraph 145 of Plaintiff's
23 Complaint.

24 146. Defendants deny the allegations contained in Paragraph 146 of Plaintiff's
25 Complaint, including all sub-parts thereof.

26 147. Defendants deny the allegations contained in Paragraph 147 of Plaintiff's
27 Complaint.

1 148. Defendants deny the allegations contained in Paragraph 148 of Plaintiff's
2 Complaint.

3 149. Defendants deny the allegations contained in Paragraph 149 of Plaintiff's
4 Complaint.

5 150. Defendants deny the allegations contained in Paragraph 150 of Plaintiff's
6 Complaint.

7 Further responding to the unnumbered Paragraph following Paragraph 150 and
8 beginning "Wherefore," Defendants aver that Plaintiff is not entitled to the relief demanded in
9 that Paragraph, and these Defendants, having answered fully, pray that this action against
10 them be dismissed and that they be awarded their costs in defending this action and that they
11 be granted such other and further relief as the Court deems just and appropriate.

12 **PUNITIVE DAMAGES ALLEGATIONS**

13 151. Defendants incorporate by reference their responses to Paragraphs 1-150 of
14 Plaintiff's Complaint as if fully set forth herein.

15 152. Defendants deny the allegations contained in Paragraph 152 of Plaintiff's
16 Complaint.

17 153. Defendants deny the allegations contained in Paragraph 153 of Plaintiff's
18 Complaint.

19 154. Defendants deny the allegations contained in Paragraph 154 of Plaintiff's
20 Complaint, including all sub-parts thereof.

21 155. Defendants deny the allegations contained in Paragraph 155 of Plaintiff's
22 Complaint.

23 156. Defendants deny the allegations contained in Paragraph 156 of Plaintiff's
24 Complaint.

PRAYER FOR RELIEF

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading “PRAYER FOR RELIEF” and beginning “WHEREFORE,” Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiff’s Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiff’s damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiff’s claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiff has been damaged, which Defendants deny, any recovery by Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or failed to mitigate her alleged damages. To the extent Plaintiff has failed to mitigate her alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

6. If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiff’s claims are barred, in whole or in

1 part, under the doctrine of federal preemption, and granting the relief requested would
2 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
3 violation of the Supremacy Clause of the United States Constitution.

4 8. If Plaintiff has been damaged, which Defendants deny, such damages were
5 caused by unforeseeable, independent, intervening, and/or superseding events for which
6 Defendants are not legally responsible.

7 9. There was no defect in the product at issue with the result that Plaintiff is not
8 entitled to recover against Defendants in this cause.

9 10. If there were any defect in the products – and Defendants deny that there were
10 any defects – nevertheless, there was no causal connection between any alleged defect and
11 the product on the one hand and any damage to Plaintiff on the other with the result that
12 Plaintiff is not entitled to recover against Defendants in this cause.

13 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
14 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
15 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
16 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
17 either in whole or in part, from all persons or entities whose negligence or fault proximately
18 caused or contributed to cause Plaintiff's alleged damages.

19 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
20 Plaintiff's Complaint were caused by the abuse, misuse, abnormal use, or use of the product
21 at issue in a manner not intended by Defendants and over which Defendants had no control.

22 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
23 Plaintiff's Complaint were caused by a substantial change in the product after leaving the
24 possession, custody, and control of Defendants.

25 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
26 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
27
28

1 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
2 Defendants.

3 15. Plaintiff's claims for breach of implied warranty must fail because the product
4 was not used for its ordinary purpose.

5 16. Defendants neither had nor breached any alleged duty to warn with respect to
6 the product, with the result that Plaintiff is not entitled to recover in this cause.

7 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
8 warnings and instructions to learned intermediaries.

9 18. At all relevant times, herein, Plaintiff's physicians were in the position of
10 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
11 benefits of the subject product.

12 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
13 entities for whose conduct Defendants are not legally responsible and the independent
14 knowledge of these persons or entities of the risks inherent in the use of the product and other
15 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
16 damages.

17 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
18 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical
19 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
20 unknown, unknowable, or not reasonably foreseeable to Defendants.

21 21. Defendants believe, and upon that ground allege, that Plaintiff was advised of
22 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
23 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
24 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
25 damages that Plaintiff seeks to recover herein.

26 22. At all relevant times during which the device at issue was designed, developed,
27 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
28

1 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
2 information, and instructions, all pursuant to generally recognized prevailing industry
3 standards and state-of-the-art in existence at the time.

4 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
5 result of the alleged conduct and do not have any right, standing, or competency to maintain
6 claims for damages or other relief.

7 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
8 estoppel, and/or laches.

9 25. If Plaintiff suffered any damages or injuries, which is denied, Defendants state
10 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
11 doctrines of contributory and/or comparative negligence.

12 26. In the further alternative, and only in the event that it is determined that
13 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
14 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
15 any other defendants, third-party defendants, or other persons, including any party immune
16 because bankruptcy renders them immune from further litigation, as well as any party, co-
17 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

18 27. Should Defendants be held liable to Plaintiff, which liability is specifically
19 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
20 from all collateral sources.

21 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
22 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
23 claims, and the prohibition on double recovery for the same injury.

24 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
25 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
26 over which Defendants had no control.

1 30. The conduct of Defendants and all activities with respect to the subject product
2 have been and are under the supervision of the Federal Food and Drug Administration
3 (“FDA”). Accordingly, this action, including any claims for monetary and/or injunctive relief,
4 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

5 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
6 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
7 their Answer to file such further pleadings as are necessary to preserve and assert such
8 defenses, claims, credits, offsets, or remedies.

9 32. The device at issue complied with any applicable product safety statute or
10 administrative regulation, and therefore Plaintiff’s defective design and warnings-based
11 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
12 comments thereto.

13 33. Plaintiff cannot show that any reasonable alternative design would have
14 rendered the Recovery® Filter inferior vena cava filter device as alleged in Plaintiff’s
15 Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f,
16 nor could Defendants have known of any alternative design that may be identified by
17 Plaintiff.

18 34. The device at issue was not sold in a defective condition unreasonably
19 dangerous to the user or consumer, and therefore Plaintiff’s claims are barred under the
20 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
21 comparable provisions of the Restatement (Third) of Torts (Products Liability).

22 35. At all relevant times during which the device at issue was designed, developed,
23 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
24 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
25 information, and instructions, all pursuant to generally recognized prevailing industry
26 standards and state-of-the-art in existence at the time.

36. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code (“UCC”) now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

37. Plaintiff’s alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors Act.

38. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

39. To the extent the claims asserted in Plaintiff’s Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendants’ rights under the Constitution of the United States and analogous provisions of the Illinois Constitution.

40. Regarding Plaintiff’s demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

41. Plaintiff’s claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the Illinois Constitution, on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs

1 satisfying a burden of proof which is less than the “beyond a reasonable doubt”
2 burden of proof required in criminal cases;

3 (b) the procedures pursuant to which punitive damages are awarded may result in
4 the award of joint and several judgments against multiple defendants for
5 different alleged acts of wrongdoing, which infringes upon the Due Process and
6 Equal Protection Clauses of the Fourteenth Amendment of the United States
7 Constitution;

8 (c) the procedures to which punitive damages are awarded fail to provide a
9 reasonable limit on the amount of the award against Defendants, which thereby
10 violates the Due Process Clause of the Fourteenth Amendment of the United
11 States Constitution;

12 (d) the procedures pursuant to which punitive damages are awarded fail to provide
13 specific standards for the amount of the award of punitive damages which
14 thereby violates the Due Process Clause of the Fourteenth Amendment of the
15 United States Constitution;

16 (e) the procedures pursuant to which punitive damages are awarded result in the
17 imposition of different penalties for the same or similar acts, and thus violate
18 the Equal Protection Clause of the Fourteenth Amendment of the United States
19 Constitution;

20 (f) the procedures pursuant to which punitive damages are awarded permit the
21 imposition of punitive damages in excess of the maximum criminal fine for the
22 same or similar conduct, which thereby infringes upon the Due Process Clause
23 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
24 Fourteenth Amendment of the United States Constitution;

25 (g) the procedures pursuant to which punitive damages are awarded permit the
26 imposition of excessive fines in violation of the Eighth Amendment of the
27 United States Constitution;
28

1 (h) the award of punitive damages to the plaintiff in this action would constitute a
2 deprivation of property without due process of law; and

3 (i) the procedures pursuant to which punitive damages are awarded permit the
4 imposition of an excessive fine and penalty.

5 42. Defendants expressly reserve the right to raise as an affirmative defense that
6 Plaintiff has failed to join all parties necessary for a just adjudication of this action, should
7 discovery reveal the existence of facts to support such defense.

8 43. Defendants reserve the right to raise such other affirmative defenses as may be
9 available or apparent during discovery or as may be raised or asserted by other defendants in
10 this case. Defendants have not knowingly or intentionally waived any applicable affirmative
11 defense. If it appears that any affirmative defense is or may be applicable after Defendants
12 have had the opportunity to conduct reasonable discovery in this matter, Defendants will
13 assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

14 **REQUEST FOR JURY TRIAL**

15 Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury
16 on all issues appropriate for jury determination.

17 **WHEREFORE**, Defendants aver that Plaintiff is not entitled to the relief demanded in
18 the Plaintiff's Complaint, and these Defendants, having fully answered, pray that this action
19 against them be dismissed and that they be awarded their costs in defending this action and
20 that they be granted such other and further relief as the Court deems just and appropriate.

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23
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25 *(Signatures on Following Page)*
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27
28

1 This 17th day of November, 2015.

2
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26 **Attorney for Defendants C. R. Bard, Inc. and**
27 **Bard Peripheral Vascular, Inc.**
28

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 17, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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